

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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:
04 md. 1603 (SHS)
:
This document relates to:
:
06 Civ. 13095 (SHS)
07 Civ. 03972 (SHS)
In re: 07 Civ. 03973 (SHS)
OXYCONTIN ANTITRUST LITIGATION : 07 Civ. 04810 (SHS)
:
CONFIDENTIAL—
:
SUBJECT TO PROTECTIVE
----- x ORDER

**DECLARATION OF CASEY B. HOWARD IN SUPPORT OF MALLINCKRODT'S
BRIEF ON THE UNENFORCEABILITY OF U.S.
PATENT NOS. 5,549,912, 5,656,295, AND 5,508,042 DUE TO INEQUITABLE CONDUCT**

CASEY B. HOWARD, an attorney duly admitted to practice law in the State of New York, hereby makes the following declaration under penalty of perjury pursuant to 28 U.S.C. § 1746:

1. I am an associate of the law firm of Lord Bissell & Brook LLP, counsel for Defendants.
2. I submit this declaration in support of Mallinckrodt's Brief on the Unenforceability of U.S. Patent Nos. 5,549,912, 5,656, 295, and 5,508,042 Due to Inequitable Conduct.
3. Attached hereto as Exhibit 1 is a true and correct copy of the opinion from *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.* No. 00-civ-8029, 2004 U.S. Dist. LEXIS 10 (S.D.N.Y. January 5, 2004.)
4. Attached hereto as Exhibit 2 is a true and correct copy of excerpts of the *Pharma L.P. v. Endo Pharmaceuticals, Inc.* No. 00-civ-8029 Trial Record.

5. Attached hereto as Exhibit 3 is a true and correct copy of notes from the International R& D Meeting, dated May 25, 1984, admitted as DTX 2194 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

6. Attached hereto as Exhibit 4 is a true and correct copy of “Final Clinical Summary-Dosing-Range Study of MS Contin 30 Mg Tablets in Patients with Chronic Pain” dated February 25, 1985 admitted as DTX 3284 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

7. Attached hereto as Exhibit 5 is a true and correct copy of a memo titled “Dosing-Range Study of Controlled-Release Oral Morphine (MS Contin) In Chronic Cancer” dated June 29, 1985, admitted as DTX 3286 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

8. Attached hereto as Exhibit 6 is a true and correct copy of U.S. Patent No. 3,965,256.

9. Attached hereto as Exhibit 7 is a true and correct copy of U.S. Patent No. 4,235,870.

10. Attached hereto as Exhibit 8 is a true and correct copy of Dr. Goldenheim’s Reply to Article (“Current Research on MS Contin”), dated June 18, 1985, admitted as DTX 3278 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

11. Attached hereto as Exhibit 9 is a true and correct copy of selected excerpts from the FDA Orange Book.

12. Attached hereto as Exhibit 10 is a true and correct copy of marketing materials for MS Contin, admitted as DTX 3260 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

13. Attached hereto as Exhibit 11 is a true and correct copy of an article titled “Steady-State Pharmacokinetics of Controlled Release Oral Morphine Sulphate in Healthy

Subjects” by Savarese, *et.al.*, admitted as DTX 2766 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

14. Attached hereto as Exhibit 12 is a true and correct copy of a chart titled “Yearly Trends in Dollar Sales” admitted as PTX 877A in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

15. Attached hereto as Exhibit 13 is a true and correct copy of U.S. Patent No. 4,834,984 admitted as DTX 2047 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

16. Attached hereto as Exhibit 14 is a true and correct copy of U.S. Patent No. 4,844,909 admitted as DTX 2063 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

17. Attached hereto as Exhibit 15 is a true and correct copy of U.S. Patent No. 4,990,341 admitted as DTX 2045 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

18. Attached hereto as Exhibit 16 is a true and correct copy of a memo from Benjamin Oshlack re: Codeine Contin, dated October 13, 1987, admitted as PTX 498 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

19. Attached hereto as Exhibit 17 is a true and correct copy of an abstract from the 1988 International Symposium on Pain Control and Medical Education titled “Clinical Pharmacology of Controlled-Release Codeine in Normal Subjects” by Kaiko *et al.*, admitted as DTX 2706 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

20. Attached hereto as Exhibit 18 is a true and correct copy of a memo from Dr. Robert Kaiko re: Controlled-Release Oxycodone, dated July 16, 1990, admitted as DTX 3165 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

21. Attached hereto as Exhibit 19 is a true and correct copy of a memo to Dr. Robert Kaiko re: OxyContin Claims, dated October 20, 1993, admitted as DTX 3156 in *Purdue v. Endo.*

22. Attached hereto as Exhibit 20 is a true and correct copy of a memo from Dr. Robert Kaiko re: OxyContin Advantages, dated September 28, 1993, admitted as DTX 3629 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

23. Attached hereto as Exhibit 21 is a true and correct copy of a memo from Dr. Robert Kaiko, dated October 4, 1993, admitted as DTX 3735 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

24. Attached hereto as Exhibit 22 is a true and correct copy of a memo from Benjamin Oshlack, dated July 24, 2002, admitted as DTX 3272 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

25. Attached hereto as Exhibit 23 is a true and correct copy of U.S. Patent No. 4,861,598 admitted as DTX 2048 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

26. Attached hereto as Exhibit 24 is a true and correct copy of U.S. Patent No. 5,266,331 admitted as DTX 2044 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

27. Attached hereto as Exhibit 25 is a true and correct copy of a chart of Purdue's Oxycodone formulations, admitted as DTX 1009 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

28. Attached hereto as Exhibit 26 is a true and correct copy of a document titled "Time Sensitive Patent Information Pursuant to 21 C.F.R. 314.53(c) for NDA #20-553," admitted as DTX 4110 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

29. Attached hereto as Exhibit 27 is a true and correct copy of the File History for U.S. Patent No., 5,266,331, admitted as PTX 7 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

30. Attached hereto as Exhibit 28 is a true and correct copy of excerpts from the July 11, 2001 deposition of Clifford Davidson taken by Boehringer Ingelheim, GMBH.

31. Attached hereto as Exhibit 29 is a true and correct copy of U.S. Patent No. 5,549,912 admitted as DTX 2049 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

32. Attached hereto as Exhibit 30 is a true and correct copy of U.S. Patent No. 5,656,295 admitted as DTX 2059 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

33. Attached hereto as Exhibit 31 is a true and correct copy of U.S. Patent No. 5,508,042 admitted as DTX 2060 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

34. Attached hereto as Exhibit 32 is a true and correct copy of excerpts from a document titled, "Oxycontin Launch Plan September 1995," admitted as DTX 3184 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

35. Attached hereto as Exhibit 33 is a true and correct copy of a memo from R. Reder re: OxyContin Tablets Investigator Survey Preliminary report, dated May 3, 1994, admitted as DTX 3739 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

36. Attached hereto as Exhibit 34 is a true and correct copy of excerpts of Purdue's OxyContin C.R. Tablets NDA #20-553 Final Study Report OC92-1001, dated February 20, 1997, admitted as PTX 717 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

37. Attached hereto as Exhibit 35 is a true and correct copy of an email from Dr. Paul Goldenheim to Dr. Robert Kaiko, dated September 3, 1996 re: OC92-1001 clinical review, admitted as DTX 4358 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

38. Attached hereto as Exhibit 36 is a true and correct copy of a document titled "1996 APS Poster Abstract Form: Comparison of Controlled Release Oxycodone Tablets to

Controlled Release Morphine in Patients with Cancer Pain,” admitted as DTX 3738 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

39. Attached hereto as Exhibit 37 is a true and correct copy of an article titled, “Controlled-release Oxycodone Compared with Controlled-Release Morphine in the Treatment of Cancer Pain: A Randomized, Double-Blind, Parallel-Group Study” by Mucci-LoRusso, *et al.*, dated 1998, admitted as DTX 2844 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

40. Attached hereto as Exhibit 38 is a true and correct copy of a study report titled “Double-Blind Randomized, Repeated Dose, Crossover Comparison of the Pharmacokinetic and Pharmacodynamic Profiles of Controlled-Release Oxycodone and Controlled-Release Morphine in Cancer Patients with Pain” by Dr. Kalso dated July 29, 1996, admitted as DTX 4355 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

41. Attached hereto as Exhibit 39 is a true and correct copy of File History for U.S. Patent No., 5,266,331, admitted as PTX 4 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

42. Attached hereto as Exhibit 40 is a true and correct copy of File History for U.S. Patent No., 5,508,042, admitted as PTX 6 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

43. Attached hereto as Exhibit 41 is a true and correct copy of File History for U.S. Patent No. 5,656,295, admitted as PTX 5 in *Purdue Pharma L.P. v. Endo Pharmaceuticals, Inc.*

44. Attached hereto as Exhibit 42 is a true and correct copy of excerpts from the July 10, 2002 deposition transcript of Dr. Robert Kaiko taken by Endo Pharmaceuticals.

45. Attached hereto as Exhibit 43 is a true and correct copy of excerpts from the June 26, 2002 deposition transcript of Dr. Robert Kaiko taken by Endo Pharmaceuticals.

46. Attached hereto as Exhibit 44 is a true and correct copy of the July 12, 2007 hearing transcript.

47. Attached hereto as Exhibit 45 is a true and correct copy of excerpts from the August 31, 2007 deposition transcript of Dr. Robert Kaiko taken by Mallinckrodt.

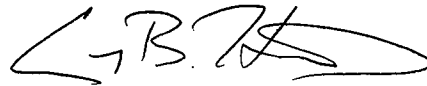
48. Attached hereto as Exhibit 46 is a true and correct copy of excerpts from the July 18, 2001 deposition transcript of Dr. Robert Kaiko taken by Boehringer Ingelheim.

49. Attached hereto as Exhibit 47 is a true and correct copy of excerpts from the July 10, 2002 deposition transcript of Joseph. Robinson taken by Endo Pharmaceuticals.

50. Attached hereto as Exhibit 48 is a true and correct copy of excerpts from the June 26, 2002 deposition transcript of Clifford Davidson taken by Endo Pharmaceuticals.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct, and that this declaration was executed on September 21, 2007, in New York, New York.

Dated: New York, New York
September 21, 2007

A handwritten signature in black ink, appearing to read 'C.B. Howard', written over a horizontal line.

Casey B. Howard